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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,511	09/29/2000	Ludwig Wolf JR.	112754-019	9637

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MARX, IRENE

ART UNIT	PAPER NUMBER
1651	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)
	09/675,511	WOLF ET AL.
	Examin er Irene Marx	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 11 March 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 28-30,32,34,36 and 38-51 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 28-30,32,34,36 and 38-51 is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____	6) <input type="checkbox"/> Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/19/02 has been entered.

DETAILED ACTION

Claims 28-30, 32, 34, 36, 38-51 are pending and are considered on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-30, 32, 34, 38-47, 49, 51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,207,107 [A] for the reasons as stated in the last Office action and the further reasons below.

US 6,207,107, claims 3-8 are directed to a method where the container which holds the body fluid has a interior constructed from a non-PVC material (claim 7) and the tubing which holds the MB solution has an inner surface of a non-PVC material (claim 6), mixing the body fluid and the MB solution and irradiating the mixture.

It is noted that applicants intend to file a Terminal Disclaimer. In the absence of this document, the rejection is maintained.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 28-30, 32, 34, 36, 38-51 remain/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28 and 40 are directed to inactivating viruses in "a body fluid". However, the specification defines "body fluid" as red cells, white cell, bone marrow, platelets (p. 6, l. 1-5), and even "internal organs" (p. 8, l. 10). Clearly, these materials are not "fluids" as defined by Webster's New World Dictionary [U]. Although the definition in the specification includes these non-fluid cells and organs, applicants cannot define a term in opposition to a generally accepted definition. In re Hill 73 USPQ 482 (CCPA 1970).

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive. While applicant may be his or her own lexicographer, as argued, a term in a claim may not be given a meaning repugnant to the usual meaning of that term, In re Hill, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "body fluid" in claims 28 and 40 is used by the claim to mean "fluid filled organ or internal structure", for while the accepted meaning is "A continuous, amorphous substance whose molecules move freely past one another and that has the tendency to assume the shape of its container; a liquid or gas." (The American Heritage® Dictionary of the English Language, Fourth Edition). Therefore, applicants' usage of the terminology "body fluid" is improper. No objective, scientific definition has been supplied which shows that, for example, an excised liver in DMEM can be considered by a person ordinarily skilled in the art, to be a "body fluid". Or that other "fluid containing structures such as internal organs" are encompassed. Please note that "fluid containing structures" as recited at page 8, paragraph 1 of the specification, encompass fluid containing organs such as bones and teeth, in addition to brain, lungs, etc. Clearly one of ordinary skill in this art would not deem such organs to constitute "body fluids" as alleged. Common sense alone would negate this interpretation which applicant continues to urge.

Amendment to replace "body fluid" with "blood or a blood component" at each occurrence would resolve this issue.

NEW MATTER

Claims 28-30, 32, 34, 36, 38, 39 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

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Insertion of the limitation "sealed" containers, has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor is there a specific example of the new limitation which would show possession of the concept of the use of "sealed" containers, as there is no exemplification contained in the specification.

This is a matter of written description, **not a question of what one of skill in the art would or would not have known**. The material within the four corners of the as-filed specification must lead to the concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of this phrase is considered to be the insertion of new matter for the above reasons.

Pointing to the passage where this limitation is recited with reference to both methylene blue and body fluid containers would overcome the rejection.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants persist in arguing that the containers of the invention are understood by one of ordinary skill in the art to be sealed. Amendment to delete the term "sealed" would resolve this issue. The allegations presented imply that the term is redundant, in any event.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 40-42, 44, 45, 49 are/remain rejected under 35 U.S.C. 102(e) as being anticipated by US 5,445,629 [B] for the reasons as stated in the last Office action and the further reasons below.

US 5,445,629 discloses a method of treating blood or blood components comprising providing methylene blue in a plastic container which has an inner liner of a non-PVC, plastic material (col. 5, l. 15); providing blood in a plastic container which may, in an embodiment, be

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PVC (col. 4, l. 3); mixing blood and photoactive agent (methylene blue) and irradiating (col. 3, l. 10).

Leaching is considered to be an inherent, passive action when methylene blue is placed in contact with plastic in the absence of evidence to the contrary.

"To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See *id.*; *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. See *Titanium Metals*, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See *id.* at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *id.* at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . . , by one who has discovered its . . . useful properties."); *Verdegaal Bros.*, 814 F.2d at 633.

This court's decision in *Titanium Metals* illustrates these principles. See *Titanium Metals*, 778 F.2d at 775. In *Titanium Metals*, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." *Titanium Metals*, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." *Id.* at 782. This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other

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doctrines, enforces that basic principle." See *Atlas Powder Co. v. IRECO Inc.* 51 USPQ2d 1943 (Fed. Cir. 1999).

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the "natural result" flowing from the reference's explicitly explicated limitations. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

In the instant case, the leaching of MB flows from the contact of a solution of MB with plastic. Please note that only one molecule of MB need migrate into the plastic to fulfill the claim limitation.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

With regard to the addition of a limitation regarding a "port" and its alleged absence in the references, it is noted that the dictionary definition of "port" is "an opening (as in a valve seat or valve face) for intake or exhaust of a fluid b : the area of opening in a cylinder face of a passageway for the working fluid in an engine; also : such a passageway". It is apparent that the reference containers both have at least one port connected to a hose.

The arguments by counsel that the container in the reference having an opening with a hose connected thereto fails to disclose a port extending from the container that provides controlled access to the container is noted. However, the cited patents specifically describe such features as of ports for controlled access (See, e.g., '107 at col. 4, lines 32-34; '629, claim 12 and Figure 1 (port 16).

Therefore, applicant's arguments are without merit and the rejection is deemed proper and it is adhered to.

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651